中 華 民 國 專 利 公 報 〔19〕〔12〕

〔11〕公告編號：347318

〔44〕中華民國87年（1998）12月11日

發 明 全 6 頁

〔51〕Int·Cl⁶：A61F13/02

〔54〕名 稱：傷口敷料

〔21〕申 請 案 號：86107606 〔22〕申請日期：中華民國86年（1997）06月03日

〔72〕發 明 人：
史丹佛包華德 瑞典
高姆德維沙特 瑞典

〔71〕申 請 人：
亞斯托股份有限公司 瑞典

〔74〕代 理 人：陳長文 先生

901>1066

初審 再審 (訴願)引證附件

1 2

[57]申請專利範圍：

1.一種用於包紮活的人體或動物體組織結構上傷口的傷口敷料，其包括當傷口敷料包紮傷口時被配置於傷口附近之下方部分，此下方部分為流體可通透性且包含促進傷口癒合過程之生物可再吸收性材料，以及上方部分，當敷料包紮傷口時係位於該下方部分之上，該上方部分對於蒸氣為可通透性且對細菌為不通透性的。

2.根據申請專利範圍第1項之傷口敷料，其特徵在於下方部分為液體可通透性。

3.根據申請專利範圍第1或2項之傷口敷料，其特徵在於傷口敷料之下方部分實質上不含揮發性溶劑。

4.根據申請專利範圍第1項之傷口敷料，其特徵在於傷口敷料為一個完整結構。

5.根據申請專利範圍第4項之傷口敷料，其特徵在於傷口敷料為具有上方與下方部分之傷口敷料形式。

6.根據申請專利範圍第5項之傷口敷料，其特徵在於傷口敷料係由上方與下方部分所組成，且下方及上方部分包含生物可再吸收性材料。

7.根據申請專利範圍第5項之傷口敷料，其特徵在於傷口敷料進而包括介於上方與下方部分間之中間部分，其適合用以吸收液體。

8.根據申請專利範圍第5項之傷口敷料，其特徵在於傷口敷料係呈薄片形式。

9.根據申請專利範圍第5項之傷口敷料，其特徵在於生物可再吸收性材料係呈微粒子或纖維形式。

10.根據申請專利範圍第5項之傷口敷料，其特徵在於傷口敷料包含生物可再吸收性材料之粒子或纖維於基質材料中。

11.根據申請專利範圍第10項之傷口敷料，其特徵在於該基質為一種凝膠基質。

12.根據申請專利範圍第11項之傷口敷

料，其特徵在於凝膠基質為透明質酸所組成。

13.根據申請專利範圍第 9 項之傷口敷料，其特徵在於傷口敷料為生物可再吸收性材料之纖維薄片。

14.根據申請專利範圍第 13 項之傷口敷料，其特徵在於傷口敷料為非織造纖維薄片。

15.根據申請專利範圍第 14 項之傷口敷料，其特徵在於傷口敷料之下方表面被粗糙化以曝露纖維之末端。

16.根據申請專利範圍第 5 項之傷口敷料，其特徵在於下方部分之生物可再吸收性材料包含一種聚合物。

17.根據申請專利範圍第 16 項之傷口敷料，其特徵在於聚合物不含蛋白質。

18.根據申請專利範圍第 17 項之傷口敷料，其特徵在於聚合物為聚(3-羥基丁酸酯，聚乳酸，聚乙醇酸，乙醇乳酸與乳酸之共聚物，乳酸與 ε -胺基己酸之共聚物，丙交酯聚合物，聚去氧　唑酮，聚(3-羥基丁酸酯)與3-羥基戊酸酯之共聚物，丁二酸與交聯透明質酸之聚酯。

19.根據申請專利範圍第 16 項之傷口敷料，其特徵在於下方部分包含聚(3-羥基丁酸酯)與寡(3-羥基丁酸酯)。

20.根據申請專利範圍第 5 項之傷口敷料，其特徵在於下方部分之生物可再吸收性材料包括聚糖類，例如脫乙醯幾丁質，膠原蛋白及蛋白質。

21.根據申請專利範圍第 5 項之傷口敷料，其特徵在於傷口敷料為有彈性的且因此使得敷料可依隨傷口之外形，例如一凹陷的傷口。

22.根據申請專利範圍第 5 項之傷口敷料，其特徵在於下方部分為多孔性。

23.根據申請專利範圍第 5 項之傷口敷料，其特徵在於傷口敷料之上方部分為多孔性。

24.根據申請專利範圍第 23 項之傷口敷料，其特徵在於下方部分為多孔性且上方部分的細孔大小比下方部分之細孔大小為小。

25.根據申請專利範圍第 23 項之傷口敷料，其特徵在於上方部分的細孔大小低於約 0.25 微米。

26.根據申請專利範圍第 1 項之傷口敷料，其特徵在於傷口敷料係以整合結構形成。

27.根據申請專利範圍第 26 項之傷口敷料，其特徵在於上方與下方部分個別藉由上方與下方傷口敷料層加以呈現，其在包紮傷口之前互相連結。

28.根據申請專利範圍第 27 項之傷口敷料，其特徵在於下方部分為多孔性。

29.根據申請專利範圍第 27 項之傷口敷料，其特徵在於下方部分為打孔的。

30.根據申請專利範圍第 27 項之傷口敷料，其特徵在於傷口敷料進而包括介於上方與下方部分間之中間部分，其係適合用以吸收液體。

31.根據申請專利範圍第 30 項之傷口敷料，其特徵在於中間部分係呈中間傷口敷料層之形式。

32.根據申請專利範圍第 30 項之傷口敷料，其特徵在於中間部分為傷口敷料之上方或下方傷口敷料層之一部分。

33.根據申請專利範圍第 27 項之傷口敷料，其特徵在於傷口敷料係由上方與下方傷口敷料層所組成，其中下方傷口敷料層被黏著至上方傷口敷料層之下方表面。

34.根據申請專利範圍第 31 項之傷口敷料，其特徵在於上方與下方傷口敷料層分別被黏著至中間傷口敷料層之上方與下方表面。

35.根據申請專利範圍第 27 項之傷口敷料，其特徵在於下方傷口敷料係可解除地被固定於傷口敷料之其餘部分。

5

36.根據申請專利範圍第35項之傷口敷料，其特徵在於下方傷口敷料層係可解除地被固定於上方傷口敷料層之下方表面。

37.根據申請專利範圍第35項之傷口敷料，其特徵在於傷口敷料進而包括介於上方與下方部分間之中間部分，其係適合用以吸收液體，中間部分係呈中間傷口敷料層之形式而下方傷口敷料層係可解除地被固定於中間傷口敷料層之下方表面。

38.根據申請專利範圍第27項之傷口敷料，其特徵在於下方傷口敷料層係藉由生物可再吸收性材料之粒子層呈現。

39.根據申請專利範圍第38項之傷口敷料，其特徵在於粒子係被維持於基質材料中。

40.根據申請專利範圍第39項之傷口敷料，其特徵在於基質為一種凝膠基質。

41.根據申請專利範圍第40項之傷口敷料，其特徵在於凝膠基質係由透明質酸所組成。

42.根據申請專利範圍第38項之傷口敷料，其特徵在於下方傷口敷料層之生物可再吸收性微粒子材料係經由在溶劑中混合粒子，將混合物塗覆至下方表面且之後蒸發溶劑而被黏著至上方或中間傷口敷料層之下方表面。

43.根據申請專利範圍第42項之傷口敷料，其特徵在於使用氯仿作為溶劑。

44.根據申請專利範圍第27項之傷口敷料，其特徵在於一或多個傷口敷料層係呈一或多個傷口敷料薄片之形式。

45.根據申請專利範圍第1項之傷口敷料，其特徵在於傷口敷料是在傷口一旦被包紮時形成。

46.根據申請專利範圍第45項之傷口敷料，其特徵在於上方與下方部分個別藉由上方與下方傷口敷料層加以呈現，其分別被施用至傷口。

6

47.根據申請專利範圍第46項之傷口敷料，其特徵在於下方部分為多孔性。

48.根據申請專利範圍第46項之傷口敷料，其特徵在於下方部分為打孔的。

49.根據申請專利範圍第46項之傷口敷料，其特徵在於傷口敷料進而包括介於上方與下方部分間之中間部分，其係適合用以吸收液體。

50.根據申請專利範圍第49項之傷口敷料，其特徵在於中間部分係呈中間傷口敷料層之形式。

51.根據申請專利範圍第49項之傷口敷料，其特徵在於中間部分為傷口敷料之上方或下方傷口敷料層之一部分。

52.根據申請專利範圍第46項之傷口敷料，其特徵在於下方傷口敷料層係藉由生物可再吸收性材料之粒子層呈現。

53.根據申請專利範圍第52項之傷口敷料，其特徵在於粒子係被維持於基質材料中。

54.根據申請專利範圍第53項之傷口敷料，其特徵在於基質為一種凝膠基質。

55.根據申請專利範圍第54項之傷口敷料，其特徵在於凝膠基質係由透明質酸所組成。

56.根據申請專利範圍第46項之傷口敷料，其特徵在於當傷口敷料包紮傷口時，下方部分係藉由放置於傷口上之生物可再吸收性材料之疏鬆粒子層或纖維層加以呈現。

57.根據申請專利範圍第46項之傷口敷料，其特徵在於下方傷口敷料層為一種凝膠，其包含被塗覆於傷口上之生物可再吸收性材料。

58.根據申請專利範圍第46項之傷口敷料，其特徵在於一或多個傷口敷料層係呈一或多個傷口敷抖薄片之形式。

59.根據申請專利範圍第58項之傷口敷料，其特徵在於下方傷口敷料層係藉由放置於傷口上之一或多個傷口敷料薄片

呈現。

60.根據申請專利範圍第27或46項之傷口敷料，其特徵在於下方傷口敷料層之生物可再吸收性材料係呈纖維形式。

61.根據申請專利範圍第 60 項之傷口敷料，其特徵在於生物可再吸收性材料係被維持於基質中。

62.根據申請專利範圍第 61 項之傷口敷料，其特徵在於生物可再吸收性材料係被維持於凝膠基質中。

63.根據申請專利範圍第 62 項之傷口敷料，其特徵在於生物可再吸收性材料係被維持於由透明質酸所形成之凝膠基質中。

64.根據申請專利範圍第 60 項之傷口敷料，其特徵在於下方傷口敷料層係藉由一或多個下方傷口敷料纖維薄片呈現。

65.根據申請專利範圍第 64 項之傷口敷料，其特徵在於一個或多個下方傷口敷料纖維薄片係由非織造纖維所形成。

66.根據申請專利範圍第 65 項之傷口敷料，其特徵在於下方傷口敷料層之下方表面係被粗糙化以曝露纖維之末端。

67.根據申請專利範圍第26或45項之傷口敷料，其特徵在於下方部分之生物可再吸收性材料包含一種聚合物。

68.根據申請專利範圍第 67 項之傷口敷料，其特徵在於聚合物不含蛋白質。

69.根據申請專利範圍第 68 項之傷口敷料，其特徵在於聚合物為聚(3-羥基丁酸酯)，聚乳酸，聚乙醇酸，乙醇酸與乳酸之共聚物，乳酸與 ε -胺基已酸之共聚物，丙交酯聚合物，聚去氧　唑酮，聚(3-羥基丁酸酯)與3-羥基戊酸酯之共聚物，丁二酸與交聯透明質酸之聚酯。

70.根據申請專利範圍第 67 項之傷口敷料，其特徵在於下方部分包括聚(3-羥基丁酸酯)與寡(3-羥基丁酸酯)。

71.根據申請專利範圍第 67 項之傷口敷

料，其特徵在於下方部分之生物可再吸收性材料包括聚糖，例如脂多糖或脫乙醯幾丁質，膠原蛋白及蛋白質。

72.根據申請專利範圍第26或45項之傷口敷料，其特徵在於傷口敷料為有彈性的且因此使得敷料可依隨傷口之外形，例如一凹陷的傷口。

73.根據申請專利範圍第27或46項之傷口敷料，其特徵在於下方傷口敷料層係適合依隨傷口之外形。

74.根據申請專利範圍第 73 項之傷口敷料，其特徵在於下方傷口敷料層為有彈性的。

75.根據申請專利範圍第 1 項之傷口敷料，其特徵在於下方部分係支援一或多種生長因子。

76.根據申請專利範圍第26或45項之傷口敷料，其特徵在於傷口敷料之上方傷口敷料層包含一種聚合物材料。

77.根據申請專利範圍第 76 項之傷口敷料，其特徵在於聚合物材料為生物可再吸收性。

78.根據申請專利範圍第 77 項之傷口敷料，其特徵在於聚合物材料不含蛋白質。

79.根據申請專利範圍第 78 項之傷口敷料，其特徵在於上方部分包含聚(3-羥基丁酸酯)。

80.根據申請專利範圍第26或45項之傷口敷料，其特徵在於上方部分包含一種非生物可再吸收性材料。

81.根據申請專利範圍第 80 項之傷口敷料，其特徵在於上方部分包含一種非生物可再吸收性聚合物材料。

82.根據申請專利範圍第 81 項之傷口敷料，其特徵在於聚合物材料為聚胺基甲酸酯或聚四氟乙烯。

83.根據申請專利範圍第26或45項之傷口敷料，其特徵在於傷口敷料之上方部分為多孔性。

9

84.根據申請專利範圍第 83 項之傷口敷料，其特徵在於下方部分為多孔性且上方部分的細孔大小比下方部分之細孔大小為小。

85.根據申請專利範圍第 83 項之傷口敷料，其特徵在於上方部分的細孔大小低於約 0.25 微米。

86.根據申請專利範圍第 1 項之傷口敷料，其特徵在於傷口敷料呈現出黏著性邊緣以黏著至傷口附近組織結構之表面。

87.根據申請專利範圍第 86 項之傷口敷料，其特徵在於上方部分及下方部分係分別由傷口敷料層及下方傷口敷料層所呈現，上方傷口敷料層呈現黏著性邊緣。

88.根據申請專利範圍第 87 項之傷口敷料，其特徵在於上方傷口敷料層完全包圍傷口敷料之其餘部分。

89.根據申請專利範圍第 87 項之傷口敷料，其特徵在於上方傷口敷料層以大約 10 至 15 毫米邊際與傷口敷料之其餘部分重疊。

90.根據申請專利範圍第 86 項之傷口敷料，其特徵在於上方部分及下方部分係分別由傷口敷料層及下方傷口敷料層所呈現，傷口敷料進而包括介於上方與下方部分間之中間部分，其係適合用以吸收液體而上方傷口敷料層包括中間部分且黏著性邊緣係藉由上方傷口敷料層之中間部分加以呈現。

10

91.根據申請專利範圍第 86 項之傷口敷料，其特徵在於上方部分及下方部分係分別由傷口敷料層及下方傷口敷料層所呈現，傷口敷料進而包括介於上方與下方部分間之中間部分，其係適合用以吸收液體，中間部分為傷口敷料之上方或下方傷口敷料層之一部分而中間傷口敷料層呈現黏著性邊緣。

92.根據申請專利範圍第30或49項之傷口敷料，其特徵在於中間部分包含水膠體。

93.一種製造傷口敷料之方法，其包括將可促進傷口癒合過程之生物可再吸收性材料的流體可通透層與蒸氣可通透性，細菌不通透層互相連結在一起。

94.根據申請專利範圍第93項之方法，其特徵在於生物可再吸收性材料為一種生物可再吸收性聚合物。

95.根據申請專利範圍第94項之方法，其特徵在於聚合物不含蛋白質。

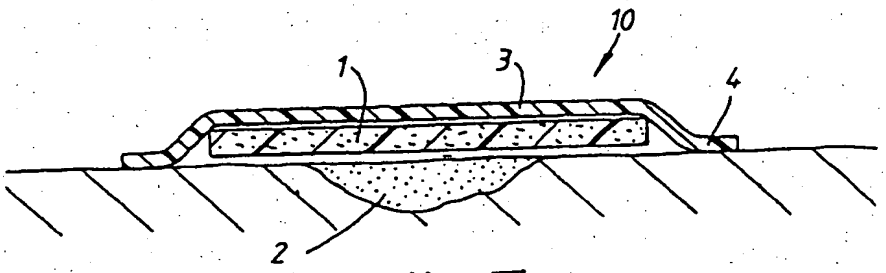
96.根據申請專利範圍第95項之方法，其特徵在於聚合物包含聚(3-羥基丁酸酯)。

圖式簡單說明：

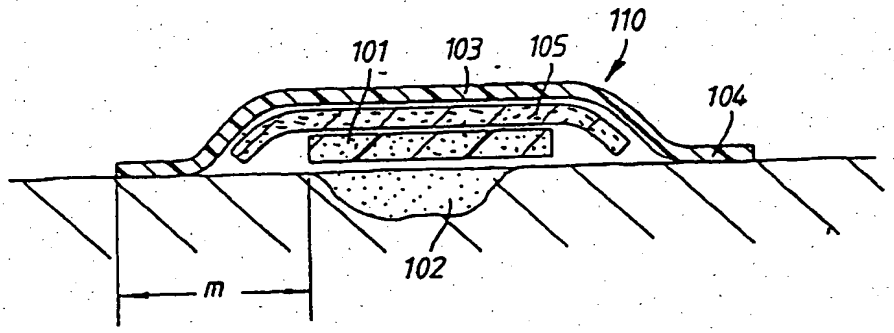
第一圖為依據本發明之第一種傷口敷料的橫斷面觀；

第二圖為依據本發明之第二種傷口敷料的橫斷面觀；及

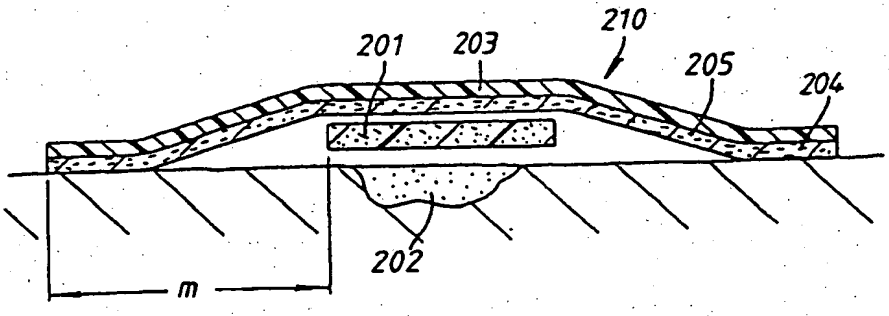
第三圖為依據本發明之第三種傷口敷料的橫斷面觀；



第一圖



第二圖



第三圖

ABSTRACT

Wound Dressing

A wound dressing (10; 110; 210) for dressing a wound (2; 102; 202) on a tissue structure of a living human or animal body comprising a lower section (1; 101; 201) which when the wound dressing dresses the wound is disposed adjacent the wound, the lower section being fluid permeable and comprising a bioresorbable material which promotes the healing process in the wound, and an upper section (3; 103; 203) which when the dressing dresses the wound overlies the lower section, the upper section being permeable to vapour and impermeable to bacteria. The wound dressing may be an integrally formed structure, an intergrated structure or formed when the wound is dressed.

(Fig. 1) .

WOUND DRESSING

The present invention relates to wound dressings for dressing of wounds on internal or external tissue structures of living human or animal bodies.

Existing wound dressings have a number of disadvantages. Conventionally, gauze dressings have been used for the treatment of wounds such as burns, cuts, abrasions and other tissue disorders. Such dressings, however, require to be changed frequently and the application and subsequent removal of a dressing for replacement with a fresh one can be painful for the patient. In fact, some dressings are so inconvenient that they may immobilise the patient.

In EP-A-0349505 (Astra Meditec AB) it is taught that the healing of soft tissue in mammals including man can be improved by the use of a porous flexible sheet of a protein-free bioresorbable polymer having a pore size which permits passage of water and salts therethrough but which locks out cells and other tissue particles. The sheet is disclosed as causing a specific stimulating effect on the formation of macrophages in soft tissue, the macrophages releasing a growth factor which stimulates tissue healing. Suitable polymer materials mentioned in EP-A-0349505 for the sheet are those based on polyglycolic acid, copolymers of glycolic acid and lactic acid, copolymers of lactic acid and ε-aminocapronic acid, lactide polymers, polydesoxazon, poly(3-hydroxybutyrate), copolymers of poly(3-hydroxybutyrate) and 3-hydroxyvalerate, polyesters of succinic acid and cross-linked hyaluronic acid. EP-A-0349505 makes known forming a non-woven sheet of poly(3-hydroxybutyrate) having the requisite properties by pressing together solution-spun fibres of poly(3-hydroxybutyrate) manufactured in accordance with US-A-4603070 (Steel et al).

As the size of the pores in the sheet of EP-A-0349505 are sufficient to allow the passage of water therethrough there is the possibility of bacteria passing through the sheet to the wound. While this might not be so problematic for the case where the sheet is for internal use, that is to say, to be disposed inside a human or animal body to cover an internal wound, it might be problematical in the case of external wounds such as skin wounds.

GB-A-2166354 (Imperial Chemical Industries Plc) discloses a wound dressing comprising a poly(3-hydroxybutyrate) polymer dissolved or swollen with a volatile solvent such as chloroform, preferably co-polymerised with 3-hydroxyvalerate units. The material is painted onto the wound as a solution or gel to give a thin film of polymer in intimate contact with the treated area. The poly(3-hydroxybutyrate) is stated to be hydrophilic, obviating the need for an outer hydrophilic layer. The dressing is stated to be particularly suitable for rapid protection of a wound site with a temporary covering.

The thin layer of hydrophilic poly(3-hydroxybutyrate) disclosed in GB-A-2166354 has a number of disadvantages as a wound dressing. To start with, there is no provision for removal of excess fluid since the layer of poly(3-hydroxybutyrate) is not particularly absorbent and exudate from the wound will not pass through it. Furthermore, it could be difficult to remove the dressing from an open wound and the volatile solvent in it tends to be cell-toxic and could cause irritation of the wound site. Moreover, the pore size distribution created in the poly(3-hydroxybutyrate) layer would be such that the size of the pores closest the wound would be less than the size of the pores remote from the wound. The possibility of infection of the wound through ingress of bacteria to the dressing therefore exists.

In summary, the prior art has not addressed the problem of providing a convenient wound dressing for use during the gradual healing of wounds that may be conveniently applied and, where needed, removed, which provides thermal insulation to maintain body temperature in the vicinity of the wound surface and keeps the wound moist yet permits removal of excessive fluid from the wound.

The present invention proposes to improve this situation.

According to the present invention there is provided a wound dressing for dressing a wound on a tissue structure of a living human or animal body which when the wound dressing dresses the wound has a lower outer surface disposed adjacent the wound, an upper outer surface spaced from the lower outer surface, a fluid permeable lower section which presents the lower outer surface and comprises a bioresorbable material which promotes the healing process of the wound and a porous upper section overlying the lower section which presents the upper outer surface, the pore size of the pores in the porous upper section being less than about 0.25μm whereby the upper section is permeable to vapour and impermeable to bacteria.

Such a dressing is relatively simple to manufacture. Moreover, the dressing is easy to apply and can be adapted to facilitate easy removal. The dressing furthermore provides thermal insulation to maintain the body temperature in the vicinity of the wound surface and keeps the wound moist while removing excessive fluid from the wound. Ensuring that the upper section is essentially impermeable to bacteria also means that a barrier is presented to prevent infection from occurring.

Transport of exudate away from the wound could be hindered if the exudate has no means of escape after it has accumulated on the upper surface of the lower section remote from the wound. The provision of an upper section which is permeable to vapour alleviates this problem by allowing the exudate to be slowly dispersed by evaporation. In addition, vapour from the tissue surrounding the wound will also be able to pass through the upper section.

The drawing of exudate from the wound into the lower section and subsequent evaporation of excess moisture creates a flux of material in the sense going away from the wound into the atmosphere. This flux further hinders the passing of bacteria in the opposite sense and thus infection from occurring.

The wound dressing of the invention may be left in place for a relatively long period. This means that fewer changes of dressing are needed than were hitherto, thus avoiding disturbing the healing process with less pain for the patient.

The use of an upper section which is vapour permeable ensures that the wound is kept moist, irrespective of how effective the removal of excessive fluid from the wound may be. Preventing the wound from drying out results in pain being controlled.

In a first form of the invention the wound dressing is an integral structure.

In a second form of the invention the wound dressing is formed as an integrated structure. For example, the upper and lower sections may respectively be presented by upper and lower wound dressing layers which are coupled to one another prior to dressing of the wound.

In a third form of the invention the wound dressing is formed once the wound is dressed, for example the upper and lower sections are respectively presented by upper and lower wound dressing layers which are applied to the wound separately.

Having the lower section of the wound dressing as a lower wound dressing layer, for instance a sheet, means that it can be easily put in position and used as a barrier facilitating the transport of exudate from the wound and retaining it away from the wound.

In an embodiment of the invention according to its various forms the wound dressing further comprises an intermediate section between the upper and lower sections which is adapted to absorb liquid. This is particularly advantageous where a large amount of exudate is encountered. For the second and third forms the intermediate section may be of any suitable material, for example treated cellulose fibres or polyacrylic acids. However, a hydrocolloid is particularly suitable. A hydrocolloid is normally able to absorb four to six times its own volume of fluid, and new hydrocolloids have been reported that absorb twenty times their own volume. Hydrocolloids also are adhesive to the skin, so the hydrocolloid can perform the dual function of intermediate absorbent layer and adhesive edge for the dressing. The intermediate section of the second and third forms of the invention may be in

the form of an intermediate wound dressing layer or instead be part of the upper or lower wound dressing layer of the wound dressing.

In an embodiment of the first form of the invention the wound dressing consists of the upper and lower sections with the lower and upper sections comprising the bioresorbable material. The bioresorbable material may be in particulate or fibre form. For example, the wound dressing may comprise particles or fibres of the bioresorbable material in a matrix material such as a gel matrix of hyaluronic acid or the like. On the other hand, the wound dressing may be a fibre sheet of the bioresorbable material, for instance a non-woven fibre sheet.

In an embodiment of the invention according to the second and third forms one or more of the wound dressing layers are in the form of one or more wound dressing sheets.

In an embodiment of the second form of the invention the wound dressing consists of the upper and lower wound dressing layers with the lower dressing layer being adhered to a lower surface of the upper wound dressing layer. Alternatively, where the wound dressing comprises the intermediate wound dressing layer the upper and lower wound dressing layers are respectively adhered to upper and lower surfaces of the intermediate wound dressing layer.

In an embodiment of the second form of the invention the lower wound dressing layer is releasably secured to the balance of the wound dressing. For example, the lower wound dressing layer may be releasably secured to the lower surface of the upper wound dressing layer or the lower surface of the intermediate wound dressing layer.

In a preferred embodiment of the invention according to its various forms the lower section of the wound dressing is substantially free of volatile solvent.

In an embodiment of the second and third forms of the invention the lower wound dressing layer is presented by a layer of particles of the bioresorbable material. The particles may be supported in a matrix material, for example a gel matrix comprising hyaluronic acid.

In an embodiment of the second form of the invention the bioresorbable particulate material of the lower wound dressing layer is adhered to the lower surface of the upper or intermediate wound dressing layer by mixing the particles in a solvent, coating the mixture to the lower surface and then evaporating the solvent. Chloroform may be mentioned as a suitable solvent.

In an embodiment of the invention according to its third form, when the wound dressing dresses the wound the lower section is presented by a layer of loose particles or fibres of the bioresorbable material positioned on the wound. Alternatively, the lower wound dressing layer may be a gel comprising the bioresorbable material coated onto the wound or one or more lower wound dressing sheets laid over the wound.

In an embodiment of the second and third forms of the invention the bioresorbable material of the lower wound dressing layer is in fibre form, for example supported in a matrix such as a gel matrix formed from hyaluronic acid. Alternately, the lower wound dressing layer may take the form of one or more lower wound dressing fibre sheets, for example formed from non-woven fibres in which case the lower surface of the lower wound dressing layer may to advantage be roughened to expose ends of the fibres.

In an embodiment of the various forms of the invention the bioresorbable material of the lower section is a polymer. For example, the polymer is protein-free, examples of which being poly(3-hydroxybutyrate) (PHB), polylactic acids, polyglycolic acid, copolymers of glycolic acid and lactic acid, copolymers of lactic acid and ε-aminocapronic acid, lactide polymers, polydesoxazon, copolymers of poly(3-hydroxybutyrate) and 3-hydroxyvalerate, polyesters of succinic acid and cross-linked hyaluronic acid.

Use of a protein-free bioresorbable polymer in the lower section appears to stimulate healing during degradation by stimulating macrophages, by forming a barrier against the surrounding and working as a scaffold for cell growth. The macrophage invasion caused by protein-free polymers covers the wound with tissue and controls the wound pain effectively in the first day or two. Vascularization and microcirculation occur, again stimulated by the polymer. Moreover, degradation of certain protein-free polymers such as PHB has a bacteriostatic and fungistatic effect and facilitates the wound healing of skin. The invading macrophages also have a bactericidal effect. The wound dressing can be left in place for a longer period owing to the bacteriostatic and fungistatic properties and the wound healing environment created beneath the dressing. Fewer changes of dressing means less disturbance of the healing process and less pain for the patient.

Poly(3-hydroxybutyrate) is the preferred material for the lower section because Applicant has found that PHB has the ability to attract macrophages to the wound site at a greater rate than other polymers tested. The PHB also appears to lead to an increased vascularization, perhaps through a macrophage effect promoted by the PHB. In addition, the dressing period is further enhanced when PHB is used due to the fact that the bacteriostatic and fungistatic properties increase over time with the degradation of the PHB.

Furthermore, in the case where the lower section is formed as a fibrous PHB sheet, for instance a non-woven sheet, having hydrophobic fibres the nature of the PHB fibres is such that the sheet has a capillary capacity which aids in the exudate being drawn away from the wound and retained in the region between the sheet and the upper section. Moreover, a non-woven PHB fibre sheet will swell during the first ten days or so by adding blood components and cells from the surrounding tissue owing to its construction despite the fibres being hydrophobic. In conclusion, a PHB fibre sheet as the lower section of the wound dressing will allow the wound to "breath" and enable vapour transport thereby leaving the wound surface with an adequate humidity.

Where poly(3-hydroxybutyrate) is selected oligo(3-hydroxybutyrate), e.g. having 3 to 10 monomer units, may also be included in the lower section or may constitute the lower section.

A wide range of other materials may be suited for the function of the lower section which would easily be apparent to a skilled reader in the art, non-limiting examples being polysaccharides such as chitosan, collagen and proteins.

In an embodiment of the various forms of the invention the wound dressing is flexible thereby enabling the dressing to follow the contour of the wound, for example a recessed wound.

In an embodiment of the second and third forms of the invention the lower wound dressing layer is adapted to follow the contour of the wound, for example by being flexible.

To assist in the wound healing process the lower section of the various forms of wound dressing according to the invention may support one or more growth factors.

In an embodiment of the second and third forms of the invention the upper wound dressing layer of the wound dressing comprises a polymeric material. The polymeric material may be bioresorbable and may further be protein-free. As an example, the upper section may comprise poly(3-hydroxybutyrate). Alternately, the upper section may comprise a non-bioresorbable non-biodegradable material, non-limiting polymeric examples being polyurethane and polytetrafluoroethylene.

Where the upper and lower sections are both porous the pore size of the pores of the upper section will be less than the pore size of the pores of the lower section.

In an embodiment of the invention according to its various forms the wound dressing presents an adhesive edge for releasably adhering to a surface of the tissue structure

adjacent the wound. This facilitates application and removal of the dressing or the upper part thereof.

In an embodiment of the second and third forms of the invention the upper wound dressing layer presents the adhesive edge in which case the upper wound dressing layer may completely surround the lower wound dressing layer. An ideal overlap margin is approximately 10 to 15 mm. Where the upper wound dressing layer includes the intermediate section, the adhesive edge may be presented by the intermediate section of the upper wound dressing layer.

In an embodiment of the second and third forms of the invention the intermediate wound dressing layer presents the adhesive edge.

Embodiments of the invention will now be described by way of example with reference to the accompanying Figures of drawings in which:-

Fig. 1 is a cross-sectional side view of a first wound dressing in accordance with the present invention;

Fig. 2 is a cross-sectional side view of a second wound dressing in accordance with the present invention; and

Fig. 3 is a cross-sectional side view of a third wound dressing in accordance with the present invention.

1; 101; 210	fluid permeable bioresorbable material layer
2; 102; 202	wound site
3; 103; 203	vapour permeable, bacteria impermeable layer
4; 104; 204	adhesive edge
10; 110; 210	wound dressing
105; 205	intermediate absorbent layer
m	margin

As can be seen from Fig. 1, a wound dressing 10 in accordance with the present invention comprises a layer 1 of a bioresorbable material which promotes wound healing processes, in this case poly(3-hydroxybutyrate) (hereinafter "PHB"), applied to a skin wound 2 in the form of a fibrous non-woven sheet substantially free of volatile solvent, and an exterior microporous layer 3 of a polyurethane polymer. The pores of the exterior polymer layer 3 have a pore size of less than 0.22 μm. This renders the layer 3 permeable to vapour and gases whilst maintaining the layer 3 essentially impermeable to bacteria.

The dressing 10 may be conveniently applied and removed and further provides thermal insulation to maintain the body temperature in the vicinity of the wound surface by virtue of the exterior polymer layer 3. The dressing 10 also keeps the wound 2 moist yet, by being permeable to moisture vapour, enables removal of excessive fluid from the wound 2. This prevents the nerve endings in the wound from drying out and concomitantly a cause of pain to the patient.

To facilitate application and removal of the dressing 10 the exterior polymer layer 3 has an adhesive edge 4.

The PHB fibres in the dressing 10 exhibit hydrophobic properties. The nature of the PHB fibres is such that exudate is drawn away from the wound 2 and retained in the PHB layer 1 and space between the PHB layer 1 and the exterior polymer layer 3.

The wound dressing 10 may be left in place for a relatively long period. This means that fewer changes of dressing are needed than with hitherto proposed dressings. This avoids disturbing the healing process with less pain for the patient. One possibility when changing the dressing 10 would be to remove the exterior layer of polymer 3 and excess exudate only, then put a fresh exterior layer 3 in place without disturbing the PHB layer 1. Alternatively, most of the PHB layer 1 may be removed as well and replaced by a fresh piece of PHB, with fibres of PHB that are adhering to the wound 2 being left.

In Fig. 2 there is shown a second wound dressing 110 in accordance with the present invention which comprises a layer 101 of PHB applied to a skin wound 102 in the form of a fibrous non-woven sheet substantially free of volatile solvent and an exterior microporous layer 103 of a polyurethane polymer. The PHB layer 101 is in the form of a patch completely surrounded by the exterior polymer layer 103 with a 10 to 15 mm margin (*m*) of the exterior polymer layer 103 around the PHB patch 101 being left. The size of the PHB patch 101 itself may vary according to the size of the wound 102.

Furthermore, an intermediate absorbent layer 105 of a hydrocolloid material is provided. This absorbs exudate that is transported away from the wound 102 by the PHB patch 101 and promotes the transport away of further exudate. The microporosity of the polyurethane exterior layer 103 means that the exudate can be slowly dispersed while still keeping the wound 102 moist and at the same time excluding bacteria. Vapour from the skin surrounding the wound 102 will also be able to pass through the exterior polymer layer 103.

The exterior polymer layer 103 has an adhesive edge 104 to facilitate application and removal of the dressing 110.

Turning now to Fig. 3, a third wound dressing 210 in accordance with the present invention comprises a layer 201 of PHB applied to a skin wound 202 in the form of a fibrous non-woven sheet substantially free of volatile solvent and an exterior microporous layer 203 of a polyurethane polymer. The PHB is again in the form of a patch completely surrounded by the exterior polymer layer 203 with a 10 to 15 mm margin (*m*) of the polymer left around the PHB patch. An intermediate absorbent layer 205 of a hydrocolloid material is again provided, but in this case the hydrocolloid layer 205 is made integral with the exterior polymer layer 203. As the hydrocolloid material is adhesive to the skin, it may be stuck to the skin by its edge 204. Thus the hydrocolloid performs the dual function of intermediate absorbent layer and adhesive edge to the exterior layer 203.

A skilled reader in the art will readily appreciate that the invention is not restricted to the specific wound dressing examples described hereinabove with reference to the accompanying drawings but that the invention may take many forms or guises within the scope of the claims.

Applicant has observed that wound dressings ought to meet the following objectives:-

- Thermal insulation should maintain body temperature of the wound surface.
- The wound should be kept moist but excess fluid should be removed.
- The dressing should be permeable to vapour but impermeable to bacteria.
- The dressing should be absorbent and breathable.
- Pain should be controlled.
- The dressing should be easy to apply and, where needed, to remove.

- The dressing should stimulate healing.

- The dressing should comply with other treatments, for example allowing an outer compressing bandage to be provided and for effective debridement of dead skin to occur.

- The dressing should be biocompatible and non-toxic.

- The dressing should not immobilise the patient.

The wound dressings hereinabove described with reference to the accompanying Figures of drawings satisfy these objectives in a simple and inexpensive manner.

In a comparative test a wound dressing in accordance with the invention and a wound dressing comprising a sheet of polyurethane (Tagerderm™) were used to dress a skin wound of a mammalian body. The dressing in accordance with the invention consisted of a lower section in the form of a non-woven fibre sheet of PHB and an upper section of a polyurethane sheet. The wound dressing of the invention produced an improved healed wound compared to the polyurethane sheet wound dressing. This was characterised by the healed wound covered by the wound dressing of the invention having a thicker and better quality layer of epithelial cells in the regenerated tissue than in the healed wound covered by the polyurethane sheet wound dressing.

第 86107606 號專利申請案
英文申請專利範圍更 正本 (88 年 6 月)
ROC (Taiwan) Patent Application No. 86107606
Amended Claims (June 1999)

1. A wound dressing for dressing a wound on a tissue structure of a living human or animal body which when the wound dressing dresses the wound has a lower outer surface disposed adjacent the wound, an upper outer surface spaced from the lower outer surface, a fluid permeable lower section which presents the lower outer surface and comprises a bioresorbable material which promotes the healing process of the wound and a porous upper section overlying the lower section which presents the upper outer surface wherein the pore size of the pores in the porous upper section is less than about 0.25μm whereby the upper section is permeable to vapour and impermeable to bacteria.

2. A wound dressing according to claim 1, characterised in that the lower section is liquid permeable.

3. A wound dressing according to claim 1 or 2, characterised in that the lower section of the wound dressing is substantially free of volatile solvent.

4. A wound dressing according to claim 1 or 2, characterised in that the bioresorbable material is in particulate or fibre form.

5. A wound dressing according to claim 4, characterised in that the particles or fibres of the bioresorbable material are in a matrix material.

6. A wound dressing according to claim 5, characterised in that the matrix is a gel matrix.

7. A wound dressing according to claim 6, characterised in that the gel matrix is of hyaluronic acid.

8. A wound dressing according to claim 1 or 2, characterised in that the bioresorbable material of the lower section comprises a polymer.

9. A wound dressing according to claim 8, characterised in that the polymer is protein-free.

10. A wound dressing according to claim 9, characterised in that the polymer is poly(3-hydroxybutyrate), a polylactic acid, polyglycolic acid, a copolymer of glycolic acid and lactic acid, a copolymer of lactic acid and ε-aminocapronic acid, a lactide polymer, polydesoxazon, a copolymer of poly(3-hydroxybutyrate) and 3-hydroxyvalerate, a polyester of succinic acid or cross-linked hyaluronic acid.

11. A wound dressing according to claim 1, characterised in that the lower section comprises poly(3-hydroxybutyrate) and oligo(3-hydroxybutyrate).

12. A wound dressing according to claim 1 or 2, characterised in that the bioresorbable material of the lower section comprises a polysaccharide such as a lipopolysaccharide, chitosan, collagen or a protein.

13. A wound dressing according to claim 1 or 2, characterised in that the lower section is porous.

14. A wound dressing according to claim 13, characterised in that the pore size of the pores of the upper section is less than the pore size of the pores of the lower section.

15. A wound dressing according to claim 1 or 2, characterised in that the lower section is perforate.

16. A wound dressing according to claim 1 or 2, characterised in that the lower section supports one or more growth factors.

17. A wound dressing according to claim 1 or 2, characterised in that the upper section comprises a non-bioresorbable material.

18. A wound dressing according to claim 17, characterised in that the upper section comprises a non-bioresorbable polymeric material.

19. A wound dressing according to claim 18, characterised in that the polymeric material is polyurethane or polyterrafluoroethylene.

20. A wound dressing according to claim 1 or 2, characterised in that the would dressing further comprises an intermediate section between the upper and lower sections which is adapted to absorb liquid.

21. A wound dressing according to claim 20, characterised in that the intermediate section comprises a hydrocolloid.

22. A wound dressing according to claim 1 or 2, characterised in that the wound dressing is an integral structure.

23. A wound dressing according to claim 22, characterised in that the wound dressing consists of the upper and lower sections with the lower and upper sections comprising the bioresorbable material.

24. A wound dressing according to claim 22, characterised in that the wound dressing is in the form of a sheet.

25. A wound dressing according to claim 23, characterised in that the wound dressing is a fibre sheet of the bioresorbable material.

26. A wound dressing according to claim 25, characterised in that the wound dressing is a non-woven fibre sheet.

27. A wound dressing according to claim 25, characterised in that the lower surface of the wound dressing is roughened to expose ends of the fibres.

28. A wound dressing according to claim 22, characterised in that the wound dressing is flexible thereby enabling the dressing to follow the contour of the wound such as a recessed wound.

29. A wound dressing according to claim 1 or 2, characterised in that the wound dressing is formed as an integrated structure.

30. A wound dressing according to claim 29, characterised in that the upper and lower sections are respectively presented by upper and lower wound dressing layers which are coupled to one another prior to dressing of the wound.

31. A wound dressing according to claim 1 or 2, characterised in that the wound dressing is formed once the wound is dressed.

32. A wound dressing according to claim 31, characterised in that the upper and lower sections are respectively presented by upper and lower wound dressing layers which are applied to the wound separately.

33. A wound dressing according o claim 31, characterised in that when the wound dressing dresses the wound the lower section is presented by a layer of loosed particles or fibres of the bioresorbable material positioned on the wound.

34. A wound dressing according to claim 32, characterised in that when the wound dressing dresses the wound the lower wound dressing layer is a gel comprising the bioresorbable material coated onto the wound.

35. A wound dressing according to claim 30, characterised in that the intermediate section is in the form of an intermediate wound dressing layer.

36. A wound dressing according to claim 30, characterised in that one or more of the wound dressing layers are in the form of one or more wound dressing sheets.

37. A wound dressing according to claim 30, characterised in that the lower wound dressing layer is adapted to follow the contour of the wound.

38. A wound dressing according to claim 37, characterised in that the lower wound dressing layer is flexible.

39. A wound dressing according to claim 30, characterised in that the upper wound dressing layer of the wound dressing comprises a polymeric material.

40. A wound dressing according to claim 39, characterised in that the polymeric material is bioresorbable.

41. A wound dressing according to claim 40, characterised in that the polymeric material is protein-free.

42. A wound dressing according to claim 41, characterised in that the upper section comprises poly(3-hydroxybutyrate).

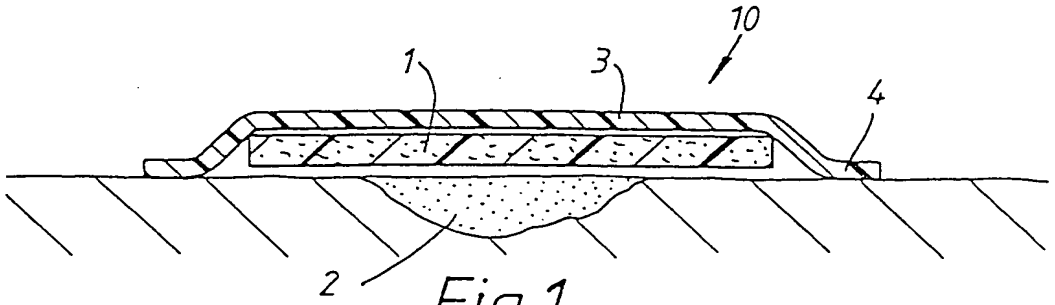


Fig.1

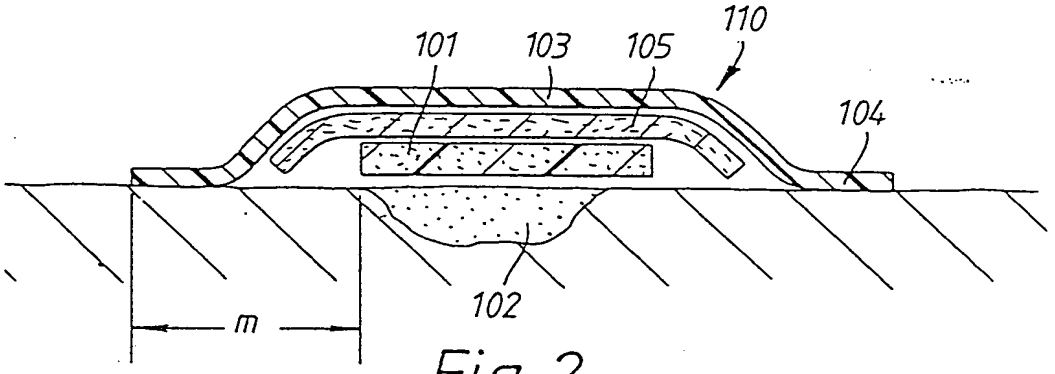


Fig.2

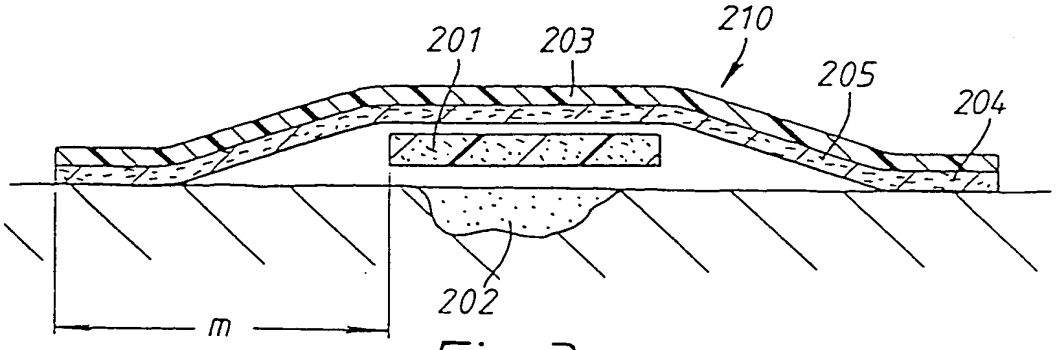


Fig.3